

R E M A R K S

Claims 1 to 71 have been cancelled. Claims 72-97 have been added.

Support for Claim 72 is found inter alia in the last three lines on page 3 to the first two lines on page 4 and in paragraph [00014], [00033], [00034], [00039]; [00057], [00058], and [00078].

Support for Claims 73 to 97 is found inter alia in the set of claims as originally filed in this application and in the specification.

According to the Official Action of November 30, 2005, the rejection of Claim 52 under 35 USC 112, first paragraph was withdrawn. However, the Examiner has rejected Claims 70 and 71 under 35 USC 112, first paragraph because of the preventing language. This rejection is respectfully traversed.

New Claim 94 corresponds to Claim 70. This claim depends from Claim 82 which defines a biologically active agent selected from the group consisting of peptide drugs, protein drugs, desensitizing agents, antigens, vaccines, anti-infectives, antibiotics, antimicrobials, antineoplastics, antitumor, antiallergenics, steroidal anti-inflammatory agents, analgesics, decongestants, miotics, anticholinergics, sympathomimetics, sedatives, hypnotics, antipsychotics, psychic energizers, tranquilizers, androgenic steroids, estrogens, progestational agents, humoral agents, prostaglandins, analgesics, antispasmodics, antimalarials, antihistamines, cardioactive agents, non-steroidal anti-inflammatory agents, antiparkinsonian agents, antihypertensive agents, beta-adrenergic blocking agents, nutritional agents, antivirals, DNA fragments, nucleic acids, RNA fragments, oligonucleotides, radioisotopes, or combinations of these classes of compounds or other forms such as uncharged molecules, molecular complexes, salts, ethers, esters, amides, and other chemically

modified forms of the biologically active agent which are biologically activated when injected into a body.

New Claim 95 corresponds to Claim 71. This claim depends from Claim 83 which defines the biologically active agents as leuprolide acetate, goserelin acetate, octreotide acetate, paclitaxel, chlorpheniramine maleate, trimethoprim, sulfamethoxazole, lactic acid, pseudoephedrine hydrochloride, olanzapine, captopril, lidocaine hydrochloride, felodipine, indomethacin, povidone iodine and terbutaline sulfate.

Claims 94 and 95 include that the health disorder, disease or medical condition can be prevented by the biologically active agent of Claim 82 or 83, respectively. These biologically active agents are known and may be used to prevent or used in the prophylaxis of specific diseases and conditions, so that one skilled in the art would be able to make and use the invention as defined in these claims. In the chemical field, there have been cases that have held that as long as the means for carrying out the invention is fully disclosed, there is no absolute requirement to include working examples in the specification and that the absence of such examples does not ipso facto mean that the patent is invalid for failure to provide enabling disclosure or describe the best mode. (In re Stephens 529 F2d 1343, 188 USPQ 659 (CCPA 1976), In re Strahilevitz 668 F2d 1229, 212 USPQ 561 (CCPA 1982)). When considering the enablement test, the person who must be able to utilize the specification to make or use the invention is one "skilled in the art to which the invention pertains or with which it is most nearly connected" and so a reasonable degree of expertise can be assumed. Therefore, one skilled in the art having knowledge of the biologically active agent would be able to make and use the invention defined in Claims 94 and 95 without undue experimentation.

Therefore, it is respectfully requested that this rejection be withdrawn.

Claim 7 has been rejected under 35 USC 112, second paragraph. This rejection is respectfully traversed.

Claim 82 corresponds to Claim 7. The term genetic material is not used in Claim 82.

Therefore, it is respectfully requested that the rejection be withdrawn.

Claims 1, 2, 5-8, 11-17, 52, 54, 55, 63 and 69-71 were rejected under 35 USC 103(a) as being obvious over Sawhney (US Patent 6,632,457). This rejection is respectfully traversed.

The arguments that were made previously are incorporated herein by reference. Claim 72 includes that a continuous hydrophobic gelled non-polymeric matrix is formed by the gelling action of a water-insoluble surfactant or emulsifier dissolved in an oily phase and that the discontinuous phase comprises a polymer. As explained in the previous response these features of the claimed invention are not disclosed nor suggested by Sawhney.

Claim 72 also provides that preformed microparticles are not used. This clearly distinguishes the claims from Sawhney. As stated in the abstract, col. 7, lines 8-27 and col. 12, lines 22-25 of Sawhney, preformed microparticles are used.

It is respectfully requested that this rejection be withdrawn.

Claims 4 and 10 were rejected under 35 USC 103(a) as being obvious over Sawhney (US Patent 6,632,457) in view of Borisy et al. (US Patent 6,569,853). This rejection is respectfully traversed.

For the reasons explained above, Claims 1, 2, 5-8, 11-17, 52, 54, 55, 63 and 69-71 are patentable over Sawhney and thus, Claims 4 and 10 are also patentable.

Therefore, it is respectfully requested that this rejection be withdrawn.

Accordingly, it is submitted that the present application is in condition for allowance and favorable consideration is respectfully requested.

Respectfully submitted,



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